Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: APERTUS PHARMACEUTICALS

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than

final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on March 20, 2014, Apertus Pharmaceuticals, 331 Consort Drive, St. Louis, Missouri 63011, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	**Schedule**
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to divide the synthesized cannabidiol, with a portion going for sale as an API in nabiximol. The raw material will be used to synthesize dronabinol. Therefore, they anticipate consuming and purchasing small quantities of CS for generating data to support the Drug Master File with the FDA including validation batches, standards and stability studies.

No other activity for this drug code is authorized for this registration.

Dated: March 20, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

OD:_____
OD/D:_____
ODX:_____OD/DX:_____ODXL:_____
ODW:_____
ODW Policy Analyst:_____
ODQ:_____
ODG:_____
ODG/ODGR - M Herron.:_____
ODG/ODGR - M. Brown:_____11/4/2014
NOA – APERTUS PHARMACEUTICALS - MFG

(DFN: 010.02.A1 General Correspondence)

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